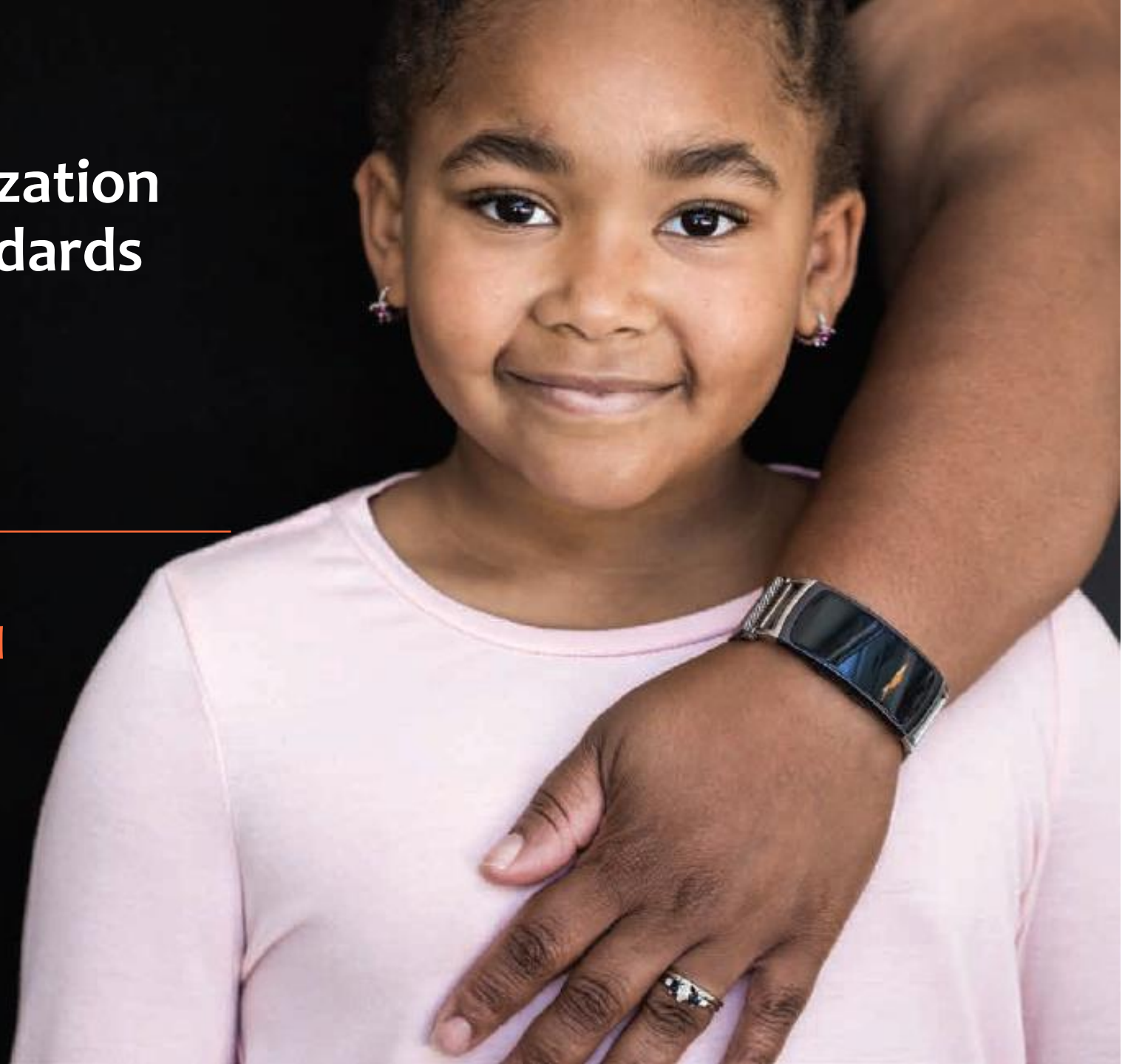


USP Processes for Prioritization and Development of Standards

Mark Wiggins, Ph.D.
Compendial Consultant with Global
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Agenda



- Introduction
- Monograph Submission Process - Stakeholder Perspective
- USP's Monograph Prioritization Process - Current Experience
- USP's Monograph Development Process - Previous Experience
- Relevant USP 2020 Resolutions
- Considerations and Conclusions



Thank You

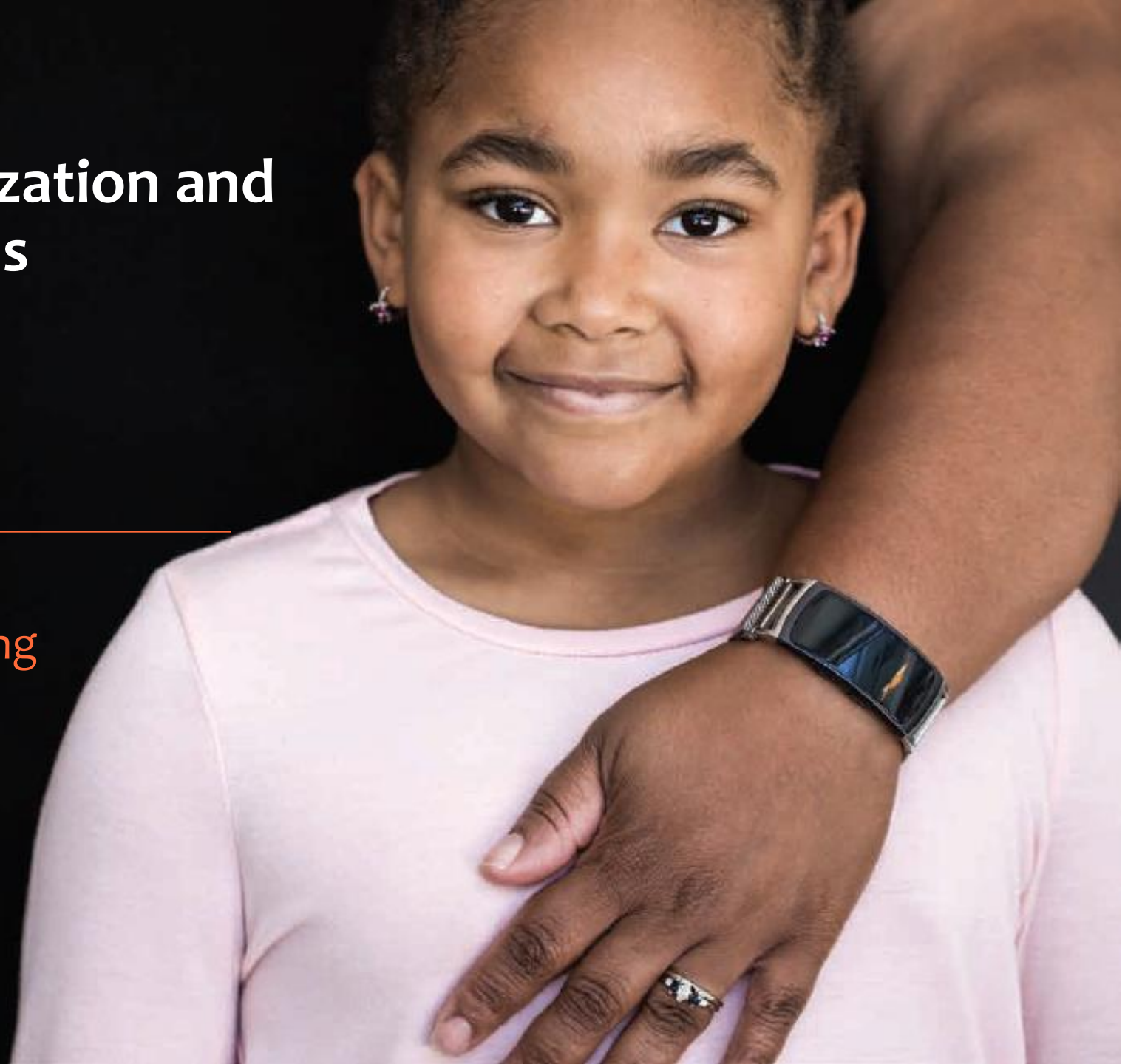


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USP Processes for Prioritization and Development of Standards

Joe Albanese

Consultant with Albanese Consulting



19 October 2021

Dear Donor,

Thank you for continuing to partner with USP by providing monograph donations that support our global public health mission. Like you, USP is committed to the continued improvement of public health through quality medicines.

Since our Up-to-Date initiative began in August 2016, USP has been successful in revising, modernizing, and developing over 1,500 documentary standards. To demonstrate our appreciation for your support and collaboration, USP's Donor Recognition Program has provided over 1.7 million USP credits to donors, like you.

Looking to the future, USP is strengthening and focusing our current processes to develop monographs that have the greatest public health impact and support making them more readily available. Part of our new focus will include evaluating current submissions and prioritizing high utilization candidates through the internal pipeline. In addition to focusing on new high priority monograph donations, we will continue addressing all public comments which may delay monograph publications.

Working with industry, our goal will be to develop monograph donations that have the highest potential of improving global public health and the largest possible impact for patients. In the coming months, USP will be evaluating our in-house submissions, as there may be some submissions that will be delayed or discontinued.

Thank You



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